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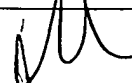
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,325	04/24/2001	Mark Modell	MDS-009CN (6219/15)	6590
21323	7590	09/01/2004	EXAMINER	
TESTA, HURWITZ & THIBEAULT, LLP HIGH STREET TOWER 125 HIGH STREET BOSTON, MA 02110			SMITH, RUTH S	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/841,325	Applicant(s) MODELL ET AL. 	
	Examiner Ruth S Smith	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 105-111, 113, 115-126 and 148-169 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 105-111, 113, 115-126, 148-150 and 152-168 is/are rejected.
- 7) ☒ Claim(s) 151 and 169 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 26, 2004 has been entered.

***Claim Objections***

Claims 151,157-158 are objected to because of the following informalities: In claim 151, it is unclear as to how an electromechanical shutter is part of a Markush grouping of materials. It is unclear as to what further structural limitation has been set forth in claims 157,158. The claims are apparatus claims but merely set forth an intended use of the apparatus. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 105-107,109,115, 120,125,126,149,150,152-157,159-161,165-167 are rejected under 35 U.S.C. 102(e) as being anticipated by Zavislan (6,424,852). The claims are directly readable on Zavislan which discloses an optical system for diagnosing tissue using a confocal illuminating and detecting arrangement. The sheath can comprises the elements shown in figures 9-11 which prevent the imager 83 from contacting the tissue. The sheath is capable of being used only a single time and can

be disposed of. The imager used in the apparatus of Zavislan is disclosed as that of US Patent No. 5,788,639 which includes beam splitters/mirrors which are moveable with respect to the patient. With respect to claim 120, the field stop is provided by the entrance to the imager 83.

Claims 105-111,113,118,120-125,148-150,152-158,161-166,168 are rejected under 35 U.S.C. 102(e) as being anticipated by DeBaryshe et al. DeBaryshe et al disclose an optical system for analyzing tissue including means for illuminating and collecting optical radiation in a substantially confocal configuration. The illuminating means and detecting means includes arrays and moveable mirrors and field stops as set forth in the claims. The system can analyze cervical tissue.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 110,158 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zavislan ('852). Zavislan discloses an optical system for diagnosing tissue using a confocal illuminating and detecting arrangement. Zavislan fails to disclose analyzing

cervical tissue. It would have been obvious to one skilled in the art that the apparatus of Zavislan would have been applicable to any tissue type.

Claims 108,111,113,118,119,121,123,148,162,168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zavislan ('852) in view of Kittrell et al. Zavislan discloses an optical system for diagnosing tissue using a confocal illuminating and detecting arrangement. Zavislan fails to disclose comparing the data obtained to a standard and the use of moveable mirrors to scan the tissue. It is well known in the medical art to obtain data from a tissue region and compare the data to at least one standard in order to properly diagnose the tissue region being tested. An example of such is seen in Kittrell et al. Kittrell et al disclose a method of optically analyzing tissue. Kittrell et al disclose illuminating the tissue using an optical assembly comprising moveable mirrors to focus the light on different regions of tissue. The structure set forth in claim 118,119 is seen in figure 23, elements 68,70. It would have been obvious to one skilled in the art to have modified Zavislan such that the data obtained is analyzed by comparing such to a known standard in order to provide a diagnosis of the tissue being tested. Furthermore, it would have been obvious to have scanned the tissue sample by using moveable mirrors rather than mechanically translating the imager. Such a modification involves the substitution of one known type of scanning means for another. With respect to claim 121 and 162, the specific field stop dimension used would have been an obvious design choice of known equivalents in the art.

Claims 116,117,122,124,163,164 rejected under 35 U.S.C. 103(a) as being unpatentable over Zavislan ('852) in view of Kittrell et al as applied to claim 108 above, and further in view of Raz. Raz discloses a confocal imaging system which uses an array of emitters and detectors in order to scan a large region of interest. It would have been obvious to one skilled in the art to have further modified Zavislan such that an array of detectors is used in order to scan a larger region of interest in a short time period. Inasmuch as Zavislan discloses the use of optical devices, the array of

detectors would require the use of optical elements and processors. The use of an array of detectors and emitters would result in an array of field stops.

***Allowable Subject Matter***

Claims 151,169 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is (703) 308-3063. The examiner can normally be reached on M-F 5:30 AM- 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ruth S Smith  
Primary Examiner  
Art Unit 3737

RSS